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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/053,869

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Hiroshi Nagasawa

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07/21/2005

BROWDY AND NEIMARK, P.L.L.C.

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WASHINGTON, DC 20001-5303

EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/053,869

**Applicant(s)**

NAGASAWA, HIROSHI

**Examiner**

BJ Forman

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 6-13 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 6-13 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 29 April 2005 in which claim 6 was amended, and claims 12-13 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 1 December 2004 are maintained. Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection, necessitated by the amendments and new claims, are discussed.

Claims 6-13 are under prosecution.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Claims 12 and 13 are drawn to the probe chip wherein the substrate comprises plastic films. The specification teaches organic films e.g. polyethylene and polyester (page 8, lines 35-38). However, the specification does not teach the newly claimed plastic films or the

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meaning or scope encompassed by the claimed plastic films. Therefore the new claims are drawn to subject matter not reasonably disclosed in the specification as filed.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 6-7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Stein et al (WO 99/59722, published 25 November 1999).

Regarding Claim 6, Stein et al discloses a probe chip comprising a plurality of stacked substrates, each having a plurality of through holes wherein the substrates are stacked to align the through-holes, a carrier filled in the through-holes wherein the carrier is porous relative to the substrate and probe molecules attached to the carrier (page 4, line 21-page 5, line 14, fig. 3-4 and 10) wherein the probe molecules attached to the surface of carriers in one groups are different from those in another group (page 8, line 17-page 9, line 23). Stein et al also teach

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the substrate is organic e.g. polyethylene (page 18, lines 10-19) as defined in the instant specification as organic (page 8, lines 37-38).

Regarding Claim 7, Stein et al discloses the method wherein the carrier is selected from the group consisting porous membrane (Fig. 7, page 21, line 23-page 22, line), non-woven fabric i.e. glass frit (page 26, lines 8-12) and a powder of porous glass i.e. 1 $\mu$ m beads (Fig. 10 and page 23, lines 10-page 25, line 11).

Regarding Claim 9, Stein et al discloses the method wherein the particle size of the glass bead is 1 to 100 $\mu$ m (page 25, lines 1-4).

Regarding Claim 10, Stein et al discloses the method wherein the probe is selected from peptides and oligonucleotides (page 8, lines 19-21).

Regarding Claim 11, Stein et al discloses the method wherein the substrates are stacked to align the through-holes of adjacent substrates in a liquid-tight manner so that liquid will not move laterally to adjacent through-holes e.g. o-ring (page 18, line 23-page 24, line 2) or sealing mechanism, Fig. 10 (page 23, lines 19-21)

#### **Response to Arguments**

7. Applicant states that the amended claims are drawn to "a stack of reaction probe chips, each of the chips being preferably flexible film or sheet made of an organic material, e.g. plastic, and most preferably in the form of a laminate of two such sheets or films laminated together with the carrier therebetween" as described in the specification, Example 2. Applicant asserts that Stein et al do not teach the newly claimed probe chips or their use as described in Example 2. Applicant specifically argues that the device of Stein et al is used for molecule synthesis and their device does not include a flexible organic substrate. The arguments have been considered but are not found persuasive because the claims are not limited to flexible substrate and because the intended use of the substrates does not limit the structure of device.

The claims are drawn to a stack of organic substrates, which the specification defines as polyethylene (page 8, lines 37-38). Stein et al teach polyethylene substrates and therefore

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teach the organic substrates as defined by the specification. Applicant's asserted flexibility of the substrates is not commensurate in scope with the claims. However, even if the asserted flexibility was required, "flexibility" is a relative term such that a substrate would be flexible when compared to one other substrate, but inflexible when compared to another.

The asserted functionality of the claimed device i.e. for binding an analyte does not define the substrate over a prior art structure having the same structural components. The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). The instant claims are drawn to stacked substrates having through-holes, the holes having a probe-attached carrier. As cited above, Stein et al teach this structure (page 4, line 21-page 5, line 14; page 8, line 17-page 9, line 23; and fig. 3-4 and 10). While, Stein et al teaches the probes may be cleaved (page 4, line 10), this is but one embodiment of their teaching. However, even if Stein et al always cleaved (which they do not) the intermediate product (pre-cleavage) meets the limitations of the claim.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stein et al (WO 99/59722, published 25 November 1999) in view of Dusterhoft et al (WO 98/08954,

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Regarding Claim 8, Stein et al discloses a probe chip comprising a plurality of stacked substrates, each having a plurality of through holes wherein the substrates are stacked to align the through-holes, a carrier filled in the through-holes wherein the carrier is porous relative to the substrate and probe molecules attached to the carrier (page 4, line 21-page 5, line 14), fig. 3-4 and 10) wherein the probe molecules attached to the surface of carriers in one groups are different from those in another group (page 8, line 17-page 9, line 23) wherein the carrier is a powder of porous glass i.e. 1 $\mu$ m beads (Fig. 10 and page 23, lines 10-page 25, line 11) and wherein the beads have perforations to provide greater surface area (page 24, lines 22-25) but is silent regarding the size of the perforation (i.e. pore size). However the claimed pore size of 0.1 to 0.5  $\mu$ m was well known in the art as preferred particles at the time the claimed invention was made as taught by Dusterhoft et al (Column 3, lines 38-40; Column 11, lines 41-60). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the preferred pore size taught by Dusterhoft et al to the particles of Stein et al et al based on the preferred teaching Dusterhoft et al (page 11, lines 58-60) and for the expected benefit of providing increased surface area as desired by Stein et al (page 24, lines 22-25).

#### **Response to Arguments**

10. Applicant asserts that Dusterhoft et al do not cure the deficiencies of Stein et al and therefore the rejection should be withdrawn. The arguments have been considered but are not found persuasive for the reasons stated above regarding Stein.

11. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein et al (WO 99/59722, published 25 November 1999).

Regarding Claims 12-13, Stein et al discloses a probe chip comprising a plurality of stacked substrates, each having a plurality of through holes wherein the substrates are

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stacked to align the through-holes, a carrier filled in the through-holes wherein the carrier is porous relative to the substrate and probe molecules attached to the carrier (page 4, line 21-page 5, line 14, fig. 3-4 and 10) wherein the probe molecules attached to the surface of carriers in one groups are different from those in another group (page 8, line 17-page 9, line 23). Stein et al also teach the substrate is organic e.g. polyethylene (page 18, lines 10-19) as defined in the instant specification as organic (page 8, lines 37-38). Stein et al specifically teaches that exemplary substrates comprise polyethylenes (page 18, lines 13-19) wherein the substrates are tightly sealed to provide liquid-tight fluid flow-through the through-holes (page 22, line 20-page 23, line 25). While they do not specifically teach heat-sealing, the courts have stated that a product is defined by the product, not by the process by which it is made.

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Furthermore, it is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to “prove that subject matter shown to be in the prior art does not possess characteristic relied on” (205 USPQ 594, second column, first full paragraph).

The claimed substrates are deemed equivalent or an obvious variation of the tightly sealed substrate of Stein et al.



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### **Prior Art**

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Leighton (U.S. Patent No. 6,136,592, filed 7 October 1999) teaches a probe chip comprising a plurality of stacked substrates having aligned through-holes each substrate comprising porous and non-porous regions (Fig. 1-2 and Column 5, lines 48-60).

### **Response to Arguments**

13. Applicant asserts that the above reference is deemed by the PTO to be insufficient to warrant application against any of the claims. Applicant's assertion is noted. However, as explicitly stated above, the reference is "considered pertinent to applicant's disclosure". The reference was cited to inform Applicant of pertinent art, and not "insufficient" art as asserted.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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### **Conclusion**

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

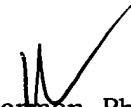
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
July 15, 2005